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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,545	10/14/2003	Clay Cannady	ATI-35	4939

40023 7590 03/01/2007
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EXAMINER	
YOO, REGINA M	
ART UNIT	PAPER NUMBER
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	**Application No.** 10/685,545	**Applicant(s)** CANNADY ET AL.	
	Examiner Regina Yoo	**Art Unit** 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 25 January 2007.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-103 is/are pending in the application.

4a) Of the above claim(s) 19-36,42,49-53,64-92,94 and 98-103 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-18,37-41,43-48,54-63,93 and 95-97 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/14/2003, 12/12/2005.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Specie A, claims 1-18, 37-41, 43-48, 54-63, 93 and 95-97 in the reply filed on January 25, 2007 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden on the Examiner to examine all of the claims. This is not found persuasive because the groups have acquired separate status in the art, it would pose a serious burden to search all three species since they would require different fields of search due to distinct parts that comprise each species. Rejoinder would be considered upon indication of all available subject matter and the basis thereof.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4-6, 10-12, 54, 56-57, 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Lickfield (5804512).

As to Claims 1 and 54, Lickfield ('512) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract; Figure 2) comprising: at least a first sheet of sterilization material (14); and a sheet of absorbent material (16; Col. 4, lines 1-22) bonded to said first sheet of sterilization material (14) (Col. 4, lines 59-60); said sheet of absorbent material (16) adapted to receive the article to be sterilized thereon (Figure 2B).

As to Claim 2, Lickfield ('512) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract; Figure 2) further including a second sheet of sterilization material (12); said second sheet of sterilization material (12) bonded to said first sheet of sterilization material (14) (Col. 4, lines 59-60).

As to Claim 4, Lickfield ('512) discloses that the sheet of absorbent material is made of cellulose (Col. 4, line 12 where cotton fiber is made of cellulose).

As to Claims 5 and 6, Lickfield ('512) discloses that the sheet of absorbent material is made of an absorbent synthetic (Col 4, lines 9-15), wherein said absorbent synthetic is taken from the group consisting of hydrophilic spunmelt polyolefins, polyester, and biocomponent fibers (Col. 3, lines 60-67 and Col. 4, lines 6-15; Col. 8, lines 51-55; Col. 9, lines 64-67 and Col. 9, lines 1-9)

As to Claim 10, Lickfield ('512) discloses that the first and second sheets of sterilization material (see Figure 2A) are made of SMS (Col. 10, lines 10-12).

As to Claim 11, Lickfield ('512) discloses that the sheet of absorbent material (16) is bonded to the first sheet of sterilization material (14) by glue (Col. 4, lines 62-64 where adhesive bonding is through use of a glue or any such material).

As to Claim 12, Lickfield ('512) discloses that the sheet of absorbent material (16) is bonded to the first sheet of sterilization material (14) by heat and pressure (Col. 9, lines 21-23 and see 76 in Figure 3).

As to Claim 56, Lickfield ('512) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract; Figure 2) comprising:

at least one sheet of sterilization material having a central portion (12; every whole/intact sheet inherently has a central portion); and

a panel (14) attached to said central portion of said sheet of sterilization material (Col. 4, lines 59-60); the basis weight of said panel (14) being higher (Col. 3, lines 58-59) than the basis weight of said sheet of sterilization material (12) (Col. 4, lines 30-33).

As to Claims 57 and 60, Lickfield ('512) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract; Figure 2) further including a sheet of absorbent material (16) attached to said panel (14) (Col. 4, lines 59-60); said sheet of absorbent material (16) enabled to wick moisture away from the article after sterilization has taken place (Col. 4, line 11).

4. Claims 37-39, 93, 95 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiss (20010023001).

As to Claims 37 and 93, Weiss ('001) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract), comprising:

at least a first sheet of sterilization material (11'); said first sheet having an outer periphery and a central portion; and

an additional sheet of material (12') being bonded (14, 15, seal regions A-C) to the central portion of said first sheet (11') (see Figures 8-11); the perimeter of said additional sheet (12') being smaller than the perimeter of said first sheet (11') (page 7, paragraph [0084] 5th-6th line; page 9, paragraph [0096]).

As to Claims 38 and 95, Weiss ('001) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract) further including a second sheet of sterilization material (13'); said second sheet of sterilization material (13') bonded (14, 15, seal regions A-C) to said first sheet of sterilization material (11') (see Figures 8-11).

As Claims 39 and 96, Weiss ('001) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract) wherein the second sheet of sterilization material (13') includes an outer periphery (see Figures 8-11); said outer periphery of said first sheet of sterilization material (11') being bonded to the outer periphery of said second sheet of sterilization material (13') (seal regions A-C; see Figure 11).

5. Claims 62 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Thukamoto (4206844).

As to Claim 62, Thukamoto ('844) discloses a sterilization wrap for wrapping an article to be sterilized (Col. 1, lines 35-39) comprising: at least one sheet of sterilization material (1); and a chemical visual indicator (5) responsive to the presence of sterilant so as to indicate whether or not the article has been exposed to adequate sterilization conditions (Col. 4, lines 22-26).

As to Claim 63, Thukamoto ('844) discloses a sterilization wrap for wrapping an article to be sterilized (Col. 1, lines 35-39) further including a second sheet (2) of sterilization material; said second sheet (2) of sterilization material bonded (4) to said first sheet (1) (Figures 1-5).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lickfield (5804512) in view of Thukamoto (4206844).

Lickfield ('512) is relied upon for disclosure described in the rejection of claim 2 under 35 U.S.C. 102(b).

Lickfield ('512) fails to teach that each of said first and second sheets of sterilization material includes four edges about their peripheries; said four edges of said first sheet of sterilization material being bonded to said four edges of said second sheet of sterilization material.

Thukamoto ('844) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract) wherein each of said first (1) and second (2) sheets of sterilization material includes four edges about their peripheries (see Figures 1,3, 5); said four edges of said first sheet of sterilization material (1) being bonded (4) to said four edges of said second sheet of sterilization material (2) (Col. 3, lines 13-14).

It was well known in the art at the time of invention to bond the two sheets of sterilization wrap along the four peripheral edges. It would have been obvious to one of ordinary skill in this art at the time of invention to provide the bonding of four peripheral edges of the first and second sheets of sterilization wrap in the wrap of Lickfield in order to ensure that the two sheets would not separate during the sterilization but would when "peeled off by hand" (Col. 3, line 16) as shown by Thukamoto and to provide another method, other than the method used by Lickfield (with "a multiplicity of thermal bonds distributed throughout" (Co. 9, lines 26-27)), to ensure that the two sheets are bonded together.

Thus, Claim 3 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Lickfield ('512) and Thukamoto ('844).

9. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lickfield (5804512) in view of Weiss (2001/0023001).

Lickfield ('512) is relied upon for disclosure described in the rejection of claim 2 under 35 U.S.C. 102(b).

As to Claim 7, Lickfield ('512) fails to teach that the sterilization wrap where the perimeter of said sheet of absorbent material is smaller than the perimeter of said first sheet of sterilization material.

Weiss ('001) discloses a sterilization wrap (10) where the perimeter of an additional sheet of sterilization material (12', 13') is smaller than the perimeter of said first sheet of sterilization material (11') (see Figures 8-11).

It was well known in the art at the time of invention to use a sheet of sterilization material that is smaller than another sheet of sterilization material in the same sterilization wrap system in terms of their perimeter. It would have been obvious to one of ordinary skill in this art at the time of invention to provide the perimeter configurations of sterilization sheets in the sterilization wrap system of Lickfield (for example, Figure 2A) in order to provide a different means to seal the sterilization wrap system onto itself so as to prevent one of the sheets of sterilization material from detaching from each other as shown by Weiss (Figure 11).

As to Claim 8, Lickfield ('512) fails to teach that the perimeter of said sheet of absorbent/additional material is at least 25% less than the perimeter of said first sheet of sterilization material, while Weiss ('001) does disclose that the perimeter of an additional sheet is about 5% less than the perimeter of the first sheet of sterilization material (page 9, paragraph [0096]), Weiss also fails to teach that the perimeter of the additional sheet is 25% less than the perimeter of the first sheet of sterilization material.

It would have been well within the purview of one of ordinary skill in the art to optimize the perimeter of the additional sheet to at least 25% less than the perimeter of said first sheet of sterilization material in order to minimize the amount of additional/absorbent sheet used in the sterilization wrap system while still achieving the same efficiency of the sterilization wrap to reduce the overall weight and cost of the system. Only the expected results would be attained.

As to Claim 9, Lickfield ('512) teach that the sterilization wrap where the first sheet of sterilization material (14) has two sides (see Figure 1); one side of said first sheet of sterilization material having a central portion (sheets inherently has a central portion until the central portion has deliberately been removed/cut out); said sheet of absorbent material (16) bonded to said first sheet of sterilization material at said central portion (see Figure 1).

Thus, Claims 7-9 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Lickfield ('512) and Weiss ('001).

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lickfield (5804512) in view of Bourne (5688476).

Lickfield ('512) is relied upon for disclosure described in the rejection of claim 2 under 35 U.S.C. 102(b).

Lickfield ('512) fails to teach that the color of the first sheet of sterilization material is different from the color of the sheet of absorbent material so that a sterile field may be readily identified.

Bourne ('476) discloses that the "shading or coloring of the inner wrap differently than the outer wrap" (Col. 8, lines 60-61).

It was well known in the art at the time of invention to impart different colors to the two sheets of the sterilization wrap. It would have been obvious to one of ordinary skill in this art at the time of invention to provide two different colors to two sheets of sterilization wrap in the sterilization wrap system of Lickfield in order for sheets to be "visually distinguishable from one another" (Col. 8, line 54) so that "proper wrap surface faces the item to be wrapped and the other [or outer] wrap surface faces away from the wrapped item" (Col. 8, lines 48-50) as shown by Bourne.

Thus, Claim 13 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Lickfield ('512) and Bourne ('476).

11. Claims 14, 15, 17-18, 55, 58-59 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lickfield (5804512) in view of Thukamoto (4206844).

As to Claims 14, 15, and 18, Lickfield ('512) is relied upon for disclosure described in the rejection of claims 1 and 2 under 35 U.S.C. 102(b).

Lickfield ('512) fails to teach that the sterilization wrap further includes a chemical visual indicator; said chemical visual indicator being in one visual state prior to exposure to sterilant and being in another visual state after exposure to sterilant; said chemical visual indicator being attached to said wrap so as to indicate whether or not the article has been exposed to adequate sterilization conditions, or that the chemical visual indicator is attached to said absorbent material.

Thukamoto ('844) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract) further including a chemical visual indicator (5); said chemical visual indicator (5) being in one visual state prior to exposure to sterilant and being in another visual state after exposure to sterilant (Col. 4, lines 22-26; Col. 5, lines 6-11); said chemical visual indicator being attached to said wrap (see Figure 1-3, 5) so as to indicate whether or not the article has been exposed to adequate sterilization conditions

(Col. 4, lines 22-26). Thukamoto ('844) discloses further that the chemical visual indicator (5) is attached to said absorbent material (1c) (Figure 2; Col. 4, lines 14-17).

It was well known in the art at the time of invention to include a chemical visual indicator within a package formed using a sterilization wrap material. It would have been obvious to one of ordinary skill in this art at the time of invention to provide a chemical visual indicator in the sterilization wrap system of Lickfield in order to obtain a means to ascertain "the completion of disinfection of a medical instrument received" with ease (Col. 4, lines 22-26) as shown by Thukamoto.

As to Claim 17, while neither Lickfield ('512) nor Thukamoto ('844) teaches that the chemical visual indicator meets the requirements of ISO 11140-1, it would have been obvious to one of ordinary skill in this art at the time of invention to use a chemical visual indicator that meets such a requirement in a sterilization wrap system of Lickfield or Thukamoto in order to demonstrate that the indicator and ultimately the sterilization wrap system achieves industry acceptable/standard level of performance.

As to Claim 55, Lickfield ('512) is relied upon for disclosure described in the rejection of claim 54 under 35 U.S.C. 102(b).

Lickfield ('512) fails to teach that the sterilization wrap further includes a chemical visual indicator; said chemical visual indicator being in one visual state prior to exposure to sterilant and being in another visual state after exposure to sterilant; said chemical visual indicator being attached to said wrap so as to indicate whether or not the article has been exposed to adequate sterilization conditions or that the chemical visual indicator is attached to said absorbent material.

Thukamoto ('844) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract) further including a chemical visual indicator (5); said chemical visual indicator (5) being in one visual state prior to exposure to sterilant and being in another visual state after exposure to sterilant (Col. 4, lines 22-26; Col. 5, lines 6-11); said chemical visual indicator being attached to said wrap (see Figure 1-3, 5) so as to indicate whether or not the article has been exposed to adequate sterilization conditions (Col. 4, lines 22-26). Thukamoto ('844) discloses further that the chemical visual indicator (5) is attached to said absorbent material (1c) (Figure 2; Col. 4, lines 14-17).

It was well known in the art at the time of invention to include a chemical visual indicator within a package formed using a sterilization wrap material. It would have been obvious to one of ordinary skill in this art at the time of invention to provide a chemical visual indicator in the sterilization wrap system of Lickfield in order to obtain a means to ascertain "the completion of disinfection of a medical instrument received" with ease (Col. 4, lines 22-26) as shown by Thukamoto.

As to Claims 58, 59 and 61, Lickfield ('512) is relied upon for disclosure described in the rejection of claims 56, 57 and 60, respectively, under 35 U.S.C. 102(b).

Lickfield ('512) fails to teach that the sterilization wrap further includes a chemical visual indicator; said chemical visual indicator being in one visual state prior to exposure to sterilant and being in another visual state after exposure to sterilant; said chemical visual indicator being attached to said wrap so as to indicate whether or not the article has been exposed to adequate sterilization conditions or that the chemical visual indicator is attached to said absorbent material.

Thukamoto ('844) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract) further including a chemical visual indicator (5); said chemical visual indicator (5) being in one visual state prior to exposure to sterilant and being in another visual state after exposure to sterilant (Col. 4, lines 22-26; Col. 5, lines 6-11); said chemical visual indicator being attached to said wrap (see Figure 1-3, 5) so as to indicate whether or not the article has been exposed to adequate sterilization conditions (Col. 4, lines 22-26). Thukamoto ('844) discloses further that the chemical visual indicator (5) is attached to said absorbent material (1c) (Figure 2; Col. 4, lines 14-17).

It was well known in the art at the time of invention to include a chemical visual indicator within a package formed using a sterilization wrap material. It would have been obvious to one of ordinary skill in this art at the time of invention to provide a chemical visual indicator in the sterilization wrap system of Lickfield in order to obtain a means to ascertain "the completion of disinfection of a medical instrument received" with ease (Col. 4, lines 22-26) as shown by Thukamoto.

Thus, Claims 14, 15, 17-18, 55, 58-59 and 61 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Lickfield ('512) and Thukamoto ('844).

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lickfield (5804512) in view of Thukamoto (4206844) as set forth above and further in view of Romito (4382063).

Lickfield ('512) and Thukamoto ('844) are relied upon for disclosure described in the rejection of claim 14 under 35 U.S.C. 103(a).

Neither Lickfield ('512) nor Thukamoto ('844) teaches that the chemical visual indicator changes color after having been exposed to steam.

Romito ('063) discloses a chemical visual indicator that changes color after having been exposed to steam (Abstract).

It was well known in the art at the time of invention to provide a chemical visual indicator that changes color after exposure to steam in a sterilization system. It would have been obvious to one of ordinary skill in this art at the time of invention to provide the chemical visual indicator for steam sterilization instead of the chemical visual indicator for ethylene oxide gas in the sterilization system of Lickfield and Thukamoto in order to "visually show that steam sterilization has been completed" (Col. 1, lines 6-7) as shown by Romito.

Thus, Claim 16 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Lickfield ('512), Thukamoto and Romito ('063).

13. Claims 40, 41, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss (20010023001) in view of Thukamoto (4206844).

As to Claims 40 and 43, Weiss ('001) is relied upon for disclosure described in the rejection of claim 39 under 35 U.S.C. 102(b).

Weiss ('512) fails to teach that the sterilization wrap further includes a chemical visual indicator; said chemical visual indicator being in one visual state prior to exposure to sterilant and being in another visual state after exposure to sterilant; said chemical visual indicator being attached to said wrap so as to indicate whether or not the article has been exposed to adequate sterilization conditions or that the chemical visual indicator is a color change indicator.

Thukamoto ('844) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract) further including a chemical visual indicator (5); said chemical visual indicator (5) being in one visual state prior to exposure to sterilant and being in another visual state after exposure to sterilant (Col. 4, lines 22-26; Col. 5, lines 6-11); said chemical visual indicator being attached to said wrap (see Figure 1-3, 5) so as to indicate whether or not the article has been exposed to adequate sterilization conditions through a color change (Col. 4, lines 22-26).

It was well known in the art at the time of invention to include a chemical visual indicator within a package formed using a sterilization wrap material. It would have been obvious to one of ordinary skill in this art at the time of invention to provide a chemical visual indicator in the sterilization wrap system of Weiss in order to obtain a means to ascertain "the completion of disinfection of a medical instrument received" with ease (Col. 4, lines 22-26) as shown by Thukamoto.

As to Claim 41, Weiss ('001) is relied upon for disclosure described in the rejection of claim 37 under 35 U.S.C. 102(b).

Weiss ('512) fails to teach that the sterilization wrap further includes a chemical visual indicator; said chemical visual indicator being in one visual state prior to exposure to sterilant and being in another visual state after exposure to sterilant; said chemical visual indicator being attached to said wrap so as to indicate whether or not the article has been exposed to adequate sterilization conditions.

Thukamoto ('844) discloses a sterilization wrap for wrapping an article to be sterilized (Abstract) further including a chemical visual indicator (5); said chemical visual indicator (5) being in one visual state prior to exposure to sterilant and being in another visual state after exposure to sterilant (Col. 4, lines 22-26; Col. 5, lines 6-11); said chemical visual indicator being attached to said wrap (see Figure 1-3, 5) so as to indicate whether or not the article has been exposed to adequate sterilization conditions (Col. 4, lines 22-26).

It was well known in the art at the time of invention to include a chemical visual indicator within a package formed using a sterilization wrap material. It would have been obvious to one of ordinary skill in this art at the time of invention to provide a chemical visual indicator in the sterilization wrap system of Weiss in order to obtain a means to ascertain "the completion of disinfection of a medical instrument received" with ease (Col. 4, lines 22-26) as shown by Thukamoto.

As to Claim 44, Weiss ('001) and Thukamoto ('844) are relied upon for disclosure described in the rejection of claim 40 under 35 U.S.C. 103(a).

While neither Weiss ('001) nor Thukamoto ('844) teaches that the chemical visual indicator meets the requirements of ISO 11140-1, it would have been obvious to one of ordinary skill in this art at the time of invention to use a chemical visual indicator that meets such a requirement in a sterilization wrap system of Weiss or Thukamoto in order to demonstrate that the indicator and ultimately the sterilization wrap system achieves industry acceptable/standard level of performance.

As to Claim 45, Weiss ('001) and Thukamoto ('844) are relied upon for disclosure described in the rejection of claim 40 under 35 U.S.C. 103(a).

Weiss ('001) fails to disclose that the chemical visual indicator is attached to the additional sheet.

Thukamoto ('844) discloses that the chemical indicator is attached to the uppermost layer of the bottom sheet defining the cavity for object to be sterilized (see Figure 2).

It was well known in the art at the time of invention to place the chemical visual indicator on the sheet in the interior of the sterilization wrap cavity for sterilization. It would have been obvious to one of ordinary skill in this art at the time of invention to provide a chemical visual indicator on the uppermost layer of the bottom sheet used to form the sterilization cavity (see Figure 2) on the additional sheet (12'), which is the uppermost layer of the bottom sheets (11' and 12'), used to form the sterilization cavity

(16) (see Figures 2-3) of Weiss in order to accurately measure the sterilant entering the cavity by physically being at the same location as the item to be sterilized as shown by Thukamoto.

Thus, Claims 40, 41, and 43-45 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Weiss ('001) and Thukamoto ('844).

14. Claims 46 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss (20010023001) in view of Lickfield (5804512).

As to Claim 46, Weiss ('001) is relied upon for disclosure described in the rejection of claim 39 under 35 U.S.C. 102(b).

While Weiss ('001) discloses that the first sheet of sterilization material is made of SMS (page 9, paragraph [0096] lines 2-6), Weiss fails to teach that the second and additional sheets of sterilization material are made of SMS.

Lickfield ('512) discloses that sterilization wrap sheets are made SMS (Col. 2, lines 33-34).

It was well known in the art at the time of invention to use SMS sheets as sterilization wrap material. It would have been obvious to one of ordinary skill in this art at the time of invention to provide a SMS sterilization wrap sheet in the sterilization wrap of Weiss in order to confer more "excellent barrier properties" (Col. 2, lines 50-54) to the sterilization wrap package as shown by Lickfield.

As to Claim 97, Weiss ('001) is relied upon for disclosure described in the rejection of claim 96 under 35 U.S.C. 102(b).

While Weiss ('001) discloses that the first sheet of sterilization material is made of SMS (page 9, paragraph [0096] lines 2-6), Weiss fails to teach that the second and additional sheets of sterilization material are made of SMS.

Lickfield ('512) discloses that sterilization wrap sheets are made SMS (Col. 2, lines 33-34).

It was well known in the art at the time of invention to use SMS sheets as sterilization wrap material. It would have been obvious to one of ordinary skill in this art at the time of invention to provide a SMS sterilization wrap sheet in the sterilization wrap of Weiss in order to confer more "excellent barrier properties" (Col. 2, lines 50-54) to the sterilization wrap package as shown by Lickfield.

Thus, Claims 46 and 97 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Weiss ('001) and Lickfield ('512).

15. Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss (20010023001) in view of Thukamoto (4206844) as set forth above and further in view of Bourne (5688476).

Weiss ('001) and Thukamoto ('844) are relied upon for disclosure described in the rejection of claim 40 under 35 U.S.C. 103(a).

While Weiss ('844) discloses the weight of the first sheet of sterilization material (page 9, paragraph [0096], lines 6-7), Weiss fails to teach the weight of the additional sheet. Thukamoto ('844) also fails to teach that the basis weight of said additional sheet is equal to or greater than the basis weight of said first sheet of sterilization material.

Bourne ('476) discloses a sterilization wrap system (10) that the basis weight of the first sheet (12) and an additional sheet (14) are equal and that the basis weight of each is 1.4 osy (Col. 9, lines 38-46).

It was well known in the art at the time of invention to use sheets of equal or varying basis weight in the sterilization wrap. It would have been obvious to one of ordinary skill in this art at the time of invention to provide the sterilization wrap sheets of the basis weight as claimed in sterilization wrap system of Weiss in order to "[adjust] the barrier and strength properties...by adjusting the basis weights of the outer and inner wraps" ('476, Col. 8, lines 3-6) as shown by Bourne.

Thus, Claims 47 and 48 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Weiss ('001) and Thukamoto ('844) and Bourne ('476).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references relate either to the field of the invention or subject matter of the invention, but are not relied upon in the rejection of record:

6537932, 3942634, 6808691, 5041264, 5082636, 6767509, 4714595, 5879620, 3494726, 6176371, 5160700.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina Yoo whose telephone number is 571-272-6690. The examiner can normally be reached on Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Piazza Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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